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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/05/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/961,414

Applicant(s)

HIRAI ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered. Applicant's amendment and response is acknowledged. Claim 4 has been amended.

Rejection Withdrawn

2. In view of Applicant's response, the rejection of claims 4 and 6-7 under 35 U.S.C. 102(a), pages 2-4 of paper no.12, mailed January 23, 2003 is withdrawn.

New Grounds of Rejection

Claim Objection

3. Claim 4 is objected to for the following informality: What appears to be a typographical error, line 6, recites "resrepresents" which should be changed to "represents". Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4 and 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by Fukuyama et al (*EP 0743 067 A2, published November 20, 1996*).

Claims 4 and 6-7 are drawn to a method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent to adsorb and remove the enterotoxin, wherein said enterotoxin is at least one selected from the group consisting of staphylococcal enterotoxins A, B, C1, C2, C3, D, E, G, H and I, said adsorbent comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier.

Fukuyama et al teach a method of removing superantigens which include enterotoxins staphylococcal enterotoxin A (SEA), staphylococcal enterotoxin B (SEB) and staphylococcal enterotoxin C (SEC) from body fluids (see the Abstract).

Fukuyama et al teach that the body fluids used in the invention can be blood, plasma or serum (page 2, lines 49-51). Fukuyama et al teach that removal of SEA, SEB and SEC from rabbit plasma (pages 5-6). Fukuyama et al teach the use of water-insoluble materials, which include porous insoluble materials that can be used in the invention (page 5). Fukuyama et al teach the use of amines in the invention such as sec-octyl-

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sec-octyl-amine, diethyleneamine, triethylenetetramine and many others (page 4).

Therefore, Fukuyama et al teach adsorbents comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier since the specification at page 7 lists amines as a preferred group of compounds having P values not smaller than 2.50. The claim limitation "wherein said water-insoluble porous carrier has a molecular weight of exclusion limit 5,000 to 600,000 for globular protein" would be inherent in the prior art. The method of Fukuyama et al, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 6-7 are rejected under 35 U.S.C. 103(a) as unpatentable over Nagaki et al, (*Journal of Med. Microbiol*, Vol. 38, 1993, 354-359) in view of Hirai et al (*EP 0 993 834 A1*, published April 19, 2000).

Claims 4 and 6-7 are drawn to a method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent to adsorb and remove the enterotoxin, wherein said enterotoxin is at least one selected from the group consisting of staphylococcal enterotoxins A, B, C1, C2, C3, D, E, G, H and I, said adsorbent comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier.

Nagaki et al teach a method for adsorptive removal of enterotoxin A from plasma of rats using various adsorbents (see the Title and the Abstract). Nagaki et al disclose a study that evaluates the capacity of various adsorbents to bind enterotoxin A and directly remove the toxin from the circulation (page 354, 2nd column). Nagaki et al teach that the direct removal of enterotoxins from the circulation may be of potential

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therapeutic value in preventing the consequences of staphylococcal septicaemia (page 354, 2nd column).

Nagaki et al do not teach the use of an adsorbent comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier.

Hirai et al teach an adsorbent comprising a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water –insoluble carrier used to eliminate toxins from body fluids by adsorption (see the Abstract). Hirai et al teach that the water-insoluble carrier is a porous carrier which has an exclusion limit for globular protein of 10,000 to 600,000 (page 5, paragraphs 0033 and 0034).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the adsorbent as taught by Hirai et al to the adsorbents used in the method for adsorptive removal of enterotoxin A from plasma of Nagaki et al because Hirai et al teach that the adsorbents comprising compound which has a log P value of at least 2.50 can used in alone or combination with compounds that have a log P value of less than 2.50 to remove toxins (page 4, paragraph 0027). It would be expected barring evidence to the contrary that the addition of the adsorbents as taught by Hirai et al to the adsorbents used in a method of removing enterotoxins from body fluids of Nagaki et al can be effective in removing enterotoxins from body fluids because Hirai et al have demonstrated that the adsorbents comprising compound which has a log P value of at least 2.50 can be used to remove toxins (i.e. toxic shock

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syndrome toxin -1 (TSST-1)) which is a toxin released by *Staphylococcus aureus* that is structurally closely related to enterotoxins (Nagaki et al, page 354, 1st column).

Additionally, the exclusion limit as described by Hirai et al for the removal of TSST-1 is within the range of the exclusion limit for the removal of the claimed staphylococcal enterotoxins.

Status of Claims

6. No claims allowed.

Conclusion

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
August 30, 2003


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